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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,335	10/08/2004	Yugo Matsunaga	259821US0PCT	2012
22850	7590	01/29/2008		
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER STOCKTON, LAURA LYNNE	
			ART UNIT 1626	PAPER NUMBER
			NOTIFICATION DATE 01/29/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/509,335	Applicant(s) MATSUNAGA ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/12/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1626

DETAILED ACTION

Claims 9-13 are pending in the application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 24, 2007 has been entered.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on applications filed in Japan. It is noted, however, that a certified copy of the

Art Unit: 1626

Japanese application filed April 8, 2002 is not present in the application. It also appears that the priority document was not submitted during the International phase. Therefore, Applicant is requested to submit a certified copy of the Japanese priority document when responding to this Office Action.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on November 12, 2007.

The rejection of Nakajima et al. under 35 USC 103 has been withdrawn. Therefore, arguments pertaining to this rejection will not be addressed.

Art Unit: 1626

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 9, Applicant has amended claim 9 by deleting what is being treated from the preamble of the claim. However, such amendment makes claim 9 indefinite because it is not clear what is being treated. It is suggested that Applicant put back the language of the ailment being treated.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in

Art Unit: 1626

public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11 and 12 of U.S. Patent No.

Art Unit: 1626

5,981,557. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant compounds of formula (1) are generically described in the claimed methods of use in the patent.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the compounds for the claimed method of use derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating epigastric pain).

One skilled in the art would thus be motivated to prepare products embraced by the patent to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, epigastric pain. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant

Art Unit: 1626

claimed invention would have been obvious to one skilled in the art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Sorbera et al. {Drugs of the Future, January 2003, Vol. 28, No. 1, pages 26-30}.

Sorbera et al. disclose that Z-338 has excellent gastroprokinetic activity (see entire document,

Art Unit: 1626

especially pages 26 and 27). Therefore, the instant claimed invention is anticipated by Sorbera et al.

Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by:

a) Nagasawa et al. {U.S. Pat. 5,981,556} - see, for instance, Example 3 in columns 41-42 and column 13, lines 32-40;

b) Nagasawa et al. {JP 10-212271} - see, for instance, the last compound shown on page 27 between columns 51-52 in the Japanese patent, the supplied abstract and the supplied partial English translation in paragraph [0011]; or

c) Nakajima et al. {J. Smooth Muscle Res. (2000), 36, pages 69-81} - see the compound of Z-338 at the top of page 70 and its having gastrointestinal motor activity.

Art Unit: 1626

Each of the above cited prior art disclose compounds embraced by instant formula (1) which are useful for the same use as instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagasawa et al. {U.S. Pat. 5,981,556} and Nagasawa et al. {JP 10-212271}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims methods of using thiazole and oxazole compounds compounds. Nagasawa et al. '556 (see

Art Unit: 1626

entire document; particularly columns 1, 2, 9 and 13; and especially Example 3 in columns 41-42) and Nagasawa et al. '271 (see entire document; particularly the supplied English abstract; and especially the last compound shown on page 27 between columns 51-52 in the Japanese patent) each teach compounds that are structurally similar to the instant formula (I) compounds that are useful in treating the same ailments.

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The difference between some of the compounds of the prior art and the compounds in the instant claimed methods of use is that the instant compounds of formula (I) are generically described in the prior art.

Finding of prima facie obviousness--rational and motivation (MPEP

§2142-2413)

Art Unit: 1626

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating dysmotility in the gastrointestinal tract).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed methods of using the products with the expectation of obtaining additional beneficial products which would be useful in treating, for example in the gastrointestinal tract. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Response to Arguments

Applicant's arguments filed September 24, 2007 have been fully considered but they are not persuasive.

Art Unit: 1626

Applicant has argued the difference in utility of the instant claimed method and the methods disclosed in the above cited prior art. Therefore, Applicant argues that the instant claimed methods of use are not anticipated under 35 USC 102 nor obvious under 35 USC 103 over any of the cited prior art.

Specifically, Applicant argue that at the time of filing Nagasawa et al. '557, the diagnostic criteria for functional dyspepsia (FD) were not completely established and thus the pathophysiological mechanism of the present invention is different from that of the reference.

All of Applicant's arguments and all of Applicant's submitted references have been considered but have not been found persuasive. Applicant argue that at the time of filing Nagasawa et al. '557, the diagnostic criteria for functional dyspepsia (FD) were not completely established and thus the pathophysiological mechanism of the present invention is different from

Art Unit: 1626

that of the reference. However, Nagasawa et al. '557 teach that their compounds are useful in treating, for example, epigastric pain (column 13, lines 38-39). Even by Applicant's own admission (page 9, first full paragraph), epigastric pain has now been identified as one of the conditions which must exist in a diagnosis of functional dyspepsia.

Applicant argues that Nakajima et al. describe the induction of gastrointestinal prokinetic action which stimulates gastric motility, which Applicant alleges is different from gastric accommodation. In response, Nakajima et al. disclose that Z-338 is useful to control gastrointestinal motility (page 80).

Further, it would appear that Applicant is relying on citing mechanisms that are not discussed in the prior art. However, if mere silence were enough, then every anticipation could be overcome by simply putting in some limitation that the reference happened to be

Art Unit: 1626

silent about, even if the material were exactly the same as the prior art. One could add limitations of physiochemical characteristics such as density, color, melting point, solubility in any solvent, etc. and then simply point to the silence of the reference. The claiming of a new use, new function or unknown property that is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In the instant case, the same patient disclosed in the prior art is being administered the same drug disclosed in the prior art for treating the same ailments disclosed in the prior art. For all the reasons given above, the rejections are deemed proper and therefore, the rejections are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is

Art Unit: 1626

(571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.



Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620
Technology Center 1600

January 22, 2008